PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 131P/PCT2	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/10891	International filing date *(day/month/year)* 08 April 2004 (08.04.2004)	Priority date *(day/month/year)* 11 April 2003 (11.04.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00; C07K 2/00 and US Cl.: 514/2; 530/300		
Applicant SOCIETE DE CONSEILS DE RECHERCHES ET		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☒ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 29 October 2004 (29.10.2004)	Date of completion of this report 25 June 2005 (25.06.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Andrew D. Kosar Telephone No. (571)272-1600

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/10891

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-86 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 87-137 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/10891

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 19

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 19

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/10891

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☒ complied with.

   ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-18 and 20-102

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/10891

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 2-18 and 20-102	YES
	Claims 1	NO
Inventive Step (IS)	Claims 2-18 and 20-102	YES
	Claims 1	NO
Industrial Applicability (IA)	Claims 1-18 and 20-102	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by SAVEANU (A. Saveanu, et al. J. Clin. Endocrin. Metabol. (2002) 87(12), pages 5545-5552).
Saveanu teaches BIM-23A237, a chimeric dopamine-somatostatin compound (throughout) and thus, claim 1 lacks novelty.

Claims 2-18 and 20-102 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the compounds of formulae (I)-(X) with dopamine compounds.

Claims 1-18 and 20-102 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 20, 27, 34, 41, and 48-102 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 20, 27, 34, 41, and 48-102 are indefinite for the following reason(s): The claims recite compounds of formulae, e.g., (I)-(X), (3), (6), etc., however there is no accompanying structure in the claim, and thus it is confusing what limitations/structures are embraced by the claims.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:
This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

1) Dop1,2,or 3 conjugates with formula (I);
2) Dop 4 conjugates with formula (II);
3) Dop5 conjugates with formula (III);
4) Dop6 conjugates with formula (IV);
5) Dop7 conjugates with formula (V);
6) Dop8 conjugates with formula (VI);
7) Dop9 conjugates with formula (VII);
8) Dop10, or 11 conjugates with formula (VIII);
9) Dop12 conjugates with formula (IX); and
10) Dop13 conjugates with formula (X).

The claims are deemed to correspond to the species listed above in the following manner:

1) claims 2, 12-18, and 20-102;
2) claims 3, 12, 13, 20, 21, 27, 28, 34, 35, 41, 42, and 48-102;
3) claims 4, 12, 13, 20, 21, 27, 28, 34, 35, 41, 42, and 48-102;
4) claims 5, 12, 20, 27, 34, 41, and 48-102;
5) claims 6, 12, 20, 27, 34, 41, and 48-102;
6) claims 7, 12, 20, 27, 34, 41, and 48-102;
7) claims 8, 12, 20, 27, 34, 41, and 48-102;
8) claims 9, 12, 20, 27, 34, 41, and 48-102;
9) claims 10, 12, 20, 27, 34, 41, and 48-102;
10) claims 11, 12, 20, 27, 34, 41, and 48-102.

The following claim(s) are generic: claim 1 is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: SAVEANU (A Saveanu, et al, J. Clin. Endocrin. Metab. (2002) 87, 5545-5552) teaches a species of the broad generic claim, a chimeric somatostatin-dopamine molecule, BIM-23A387 (Title, Abstract, throughout).
is taught by Saveanu. Further, according to PCT Rule 13.2 and the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the chemical compounds of Claims 2-11 share a common property of being dopamine and/or somatostatin agonists, the compounds are not regarded as being of similar nature because all of the alternatives do not share a common structure, and are not an art recognized class of compounds. Each of the groups recites distinct somatostatin agonists which are linked to distinct dopamine agonists, and the chimeric compounds are not a recognized class of compound in the art, therefore the species lack unity of invention.